AUG 9 - 2005

K051796

510(k) SUMMARY

1. Submitter

1) Name	KURARAY MEDICAL INC.
2) Address	1621 Sakazu, Kurashiki, Okayama 710-8622, Japan
3) 1. Contact person	Masaya Sasaki Dental Material Division, Kuraray Medical Inc.
2. Contact person in U.S.A.	Satoshi Yamaguchi Kuraray America Inc. 101 East 52nd Street, 26th Floor New York, NY 10022 Telephone: (212)-986-2230 (Ext.115) 1-(800)-879-1676 Facsimile: (212)-867-3543
4) Date	October XX, 2004

2. Name of Device

1) Proprietary Name	Clearfil tri-S bond Single dose
2) Classification Name	Resin tooth bonding agent (21CFR 872.3200)
3) Common/Usual Name	Resin-based dental adhesive system

3. Predicate device

The predicate device is as follow;

a) Resin Tooth Bonding Agent

1. Clearfil tri-S bond by Kuraray Medical Inc. (K042913)

4. Description for the premarket notification

This device is classified into the resin tooth bonding agent, CFR 21 Section 872.3200, because it is a device composed of materials such as dimethacrylate monomers intended to be painted on the interior of a prepared cavity of a tooth to improve retention of restorative materials.

5. Statement of the intended use

The intended use of this device is as follows. It is the same as that of Clearfil tri-S bond (K042913) manufactured by Kuraray Medical Inc.

Indications for Use	Predicate device
1) Direct restorations using light-cured composite resin 2) Cavity sealing as a pretreatment for indirect restorations 3) Treatment of exposed root surfaces 4) Core build-ups using light- or dual-cured composite resin	Clearfil tri-S bond (K042913)

6. Statement of the safety and technological characteristics

6-1. Safty

The ingredients and composition of this device are the same as that of Clearfil tri-S bond (K042913) and it only differs in that it is filled in single dose tips (disposable tips). Therefore this device is the same as the legally marketed predicate devices, Clearfil tri-S bond, in respect of safety.

6-2. Technological characteristics

The bond strengths between bovine tooth and a composite resin, between bovine dentin and core build up composite resin and marginal sealing were evaluated in comparison with Clearfil tri-S bond . As to the result, this device is substantially equivalent to the legally marketed predicate devices, Clearfil tri-S bond, in effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 9 - 2005

Kuraray Medical, Incorporated
C/O Mr. Satoshi Yamaguchi
Kuraray America, Incorporated
101 East 52nd Street, 26th Floor
New York, New York 10022

Re: K051796
Trade/Device Name: Clearfil™ tri-S Bond Single Dose
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: July 01, 2005
Received: July 12, 2005

Dear Mr. Yamaguchi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K051796

Device Name: Clearfil tri-S bond Single dose

Indications for Use

Clearfil tri-S bond Single dose is indicated for the following applications:

1) Direct restorations using light-cured composite resin
2) Cavity sealing as a pretreatment for indirect restorations
3) Treatment of exposed root surfaces
4) Core build-ups using light- or dual-cured composite resin

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K051796